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10/761,787

01/21/2004

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EXAMINER

KIM, JENNIFER M

ART UNIT

PAPER NUMBER

1617

NOTIFICATION DATE

DELIVERY MODE

10/22/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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|------------------------------|-------------------------------|-------------------------------|--|
| Office Action Summary | Application No. 10/761,787 | Applicant(s) WEINER ET AL. | |
| | Examiner Jennifer Kim | Art Unit 1617 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 59-81 is/are pending in the application.
- 4a) Of the above claim(s) 59 and 61-64 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 60, 65-81 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>8/21/07, 7/19/04, 4/23/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' election without traverse of Group I, claims 1-9, drawn to a method of treating **psychosis** comprising identifying a subject suffering from one or more symptoms of psychosis; contacting said subject with a therapeutically effective amount of N-desmethylozapine; whereby the one or more symptoms of **psychosis** are ameliorated, and Aripiprazole as an elected species of additional therapeutic agent is acknowledged. Accordingly, claims 1-9, 60 and 65-81 have been examined to the extent of Applicants' elected species Aripiprazole as an additional therapeutic agent. Claims 59 and 61-64 have been withdrawn from consideration since they are non-elected invention, as they do not read on elected species.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9, 60 and 65-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmutz et al. (U.S. Patent No. 3,389,139) in view of Tamminga et al. (2002).

Schmutz et al. teach that N-desmethylozapine is useful as neuroleptics and therefore suitable for the treatment of psychotic conditions. (column 1, lines 39-44, column 5, lines 1-4, Table II, compound 11). Schmutz et al. teach that N-desmethylozapine can be administered in the form of pharmaceutical preparations including tablets or solutions for injection in dosage unit containing 1 to 50mg. Schmutz et al. teach that the N-desmethylozapine, depending on its nature, on the route of administration and on the physician's prescription, the effective daily dosage amounting to from 10 to 500mg. (column 5, lines 5-15). These amounts are within and overlaps Applicants amounts set forth in claim 71.

Schmutz et al. do not teach the specific symptoms of psychosis, the mechanism of action of increasing a level of activity of a muscarinic receptor, combination with Aripiprazole, and the subject having additional medical condition set forth in claims 74-75.

Tamminga et al. teach that Aripiprazole is useful for the treatment of psychosis because it delivers full antipsychotic action equal to haloperidol. (abstract, page 144 under C. Aripiprazole). Tamminga et al. teach that psychosis is a symptom of abnormal mental function characterized by thought disorder, paranoia, hallucinations delusions and dementia. Tamminga et al. teach that Aripiprazole has advantages in the treatment of affect control and cognitive performance. (abstract, last sentence).

It would have been obvious to one of ordinary skill in the art to employ N-desmethylozapine for the treatment of symptoms of psychosis because Schmutz et al. teach that N-desmethylozapine is suitable for the treatment of psychotic conditions. One would have been motivated to employ N-desmethylozapine for the treatment of symptoms of psychosis taught by Tamminga et al. in order to achieve an expected benefit of effectiveness of N-desmethylozapine in the treatment of psychotic conditions taught by Schmutz et al. Moreover, to further combine Aripiprazole in the treatment of psychosis with N-desmethylozapine would have been obvious because Aripiprazole is also useful for the treatment of psychosis and advantages in cognitive performance in view of Tamminga et al. The motivation for combining the components flows from their individually known common utility (see *In re Kerkhoven*, 205 USPQ 1069(CCPPA 1980)). Further, the mechanism of action of increasing a level of activity

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of muscarinic receptor set forth in claim 1 is obvious because a mechanism by which the active ingredient gives the pharmacological effect does not alter the fact that the compound has been previously used to obtain the same pharmacological effects which would result from the claimed method. The patient, condition (psychosis) to be treated and the effect are the same. With regard to the psychosis patient being treated having neurodegenerative conditions such as Alzheimer does not make unobvious because a patient suffering from such disorder generally suffers and has symptoms of psychosis and cognitive dysfunction.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9, 60 and 65-81 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10-21 of copending Application No. 10/913,117; claims 1-6 and 19-29 of copending Application No. 11/098,892; claims 1-8 of copending Application No. 11/671,405; and claims 1-5 and 15 of copending Application No. 11/416,565. Although the conflicting claims are not identical, they are not patentably distinct from each other because they encompass the same subject matter of treating psychotic condition or symptoms of psychosis comprising the same active agent N-desmethylozapine. As such, the claims of the instant Application and the claims in the copending Applications would have been obvious variations of the other to one of ordinary skill in the art. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.


Communication

The information disclosure statement (IDS) submitted on 8/21/2007, 7/19/2004 and 4/23/2004 were considered by the examiner. However, the reference of FR51 of IDS filed 7/19/2004 was not initialed by the Examiner because it appears to a typographical error.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Jennifer Kim
Primary Examiner
Art Unit 1617

Jmk
October 14, 2007